November 18, 2005

Mr. Mike Gallagher, PBT Coordinator
Department of Ecology
P.O. Box 47600
WA, 98504
mgal461@ecy.wa.gov

Re: Draft PBT Rule (Chapter 173-333 WAC, October 2005 Draft)

Dear Mr. Gallagher:

The North American Metals Council ("NAMC") appreciates the opportunity to provide comments on the Washington Department of Ecology's ("Ecology") October 2005 Draft Rule entitled "Persistent Bioaccumulative Toxins" ("Draft PBT Rule"), which would be codified as Chapter 173-333 WAC. NAMC is an unincorporated not-for-profit group of metals-producing and metals-using associations and companies that focuses on science and policy matters that affect metals in a generic way.

For several years, NAMC has been actively involved in discussions at the U.S. Environmental Protection Agency ("U.S. EPA") and elsewhere regarding the scientific validity of applying to metals hazard criteria based on persistence, bioaccumulation, and toxicity ("PBT") that were initially developed for organic compounds. Ecology's Draft PBT Rule directly raises this issue. For the reasons explained below, NAMC urges Ecology to reject the current draft's attempt to extend the use of PBT criteria to the hazard assessment of metals. Refraining from including metals on the PBT list in no way limits Ecology or other Washington state agencies from taking actions necessary to reduce risks to human health or the environment posed by exposures to lead, cadmium, mercury, or any other metal.

The Draft PBT Rule would identify a metal as a PBT chemical if it is found to meet general PBT criteria and if "ecology determines that [the metal] is likely to be present in forms that are bioavailable." Draft PBT Rule, Section 173-333-320 (2)(d). Indeed, the metals cadmium and lead, as well as mercury, are included in the PBT list in Section 173-333-310 (2) of the Draft PBT Rule. In an apparent effort to honor in some fashion a commitment Ecology previously made, the proposed Rule would list these metals as PBT chemicals but hold off developing a chemical action plan for them until U.S. EPA concludes its efforts to develop a metals assessment framework and Ecology completes a review of bioavailability of the listed metals. Draft PBT Rule, Section 173-333-310 (3). This approach is inconsistent with the actual commitment Ecology made and also with current, "credible scientific information," the stated basis underlying Ecology's proposed PBT criteria, *see* Summary, Technical Background Information for The Proposed PBT List, October 2005 (Revised Draft).

Ecology's Commitment

The treatment of metals in the Draft PBT Rule is contrary to a commitment Ecology made in 2002, after being advised that U.S. EPA was conducting a comprehensive scientific review of the question whether PBT criteria can appropriately be applied to metals.

As Ecology stated in a letter dated March 5, 2002:

> Ecology has learned that EPA will be working with its Science Advisory Board to develop comprehensive cross-agency guidance for assessing the hazards and risks of metals. Until this issue posed to EPA's Science Advisory Board is addressed, Ecology will include a footnote on any PBT Working List identifying that any metals on the working list are currently undergoing this review and that Ecology will revise any PBT working list so as to be consistent with EPA waste minimization treatment of metals.[1]

EPA's current waste minimization program identifies two sets of "priority chemicals": 27 organic chemical substances that were selected using PBT criteria, and three metals which are separately listed.[2] EPA explicitly states that it did *not* list the three metals on the basis of PBT criteria:

> In its 1998 Notice, EPA identified these metals as Priority Chemicals using the same PBT analysis framework that it used for organic chemicals. EPA subsequently decided to defer the use of that framework and is working with its Science Advisory Board to develop a consistent, Agency-wide approach for the evaluation of metals.[3]

Accordingly, if Ecology is to fulfill its commitment to "revise any PBT working list so as to be consistent with EPA waste minimization treatment of metals," the Draft PBT rule may not list metals through use of PBT criteria.

Credible Scientific Information

EPA's Science Advisory Board ("SAB") review of the agency's draft Metals Risk Assessment Framework is still ongoing. *See* http://www.epa.gov/sab/panels/mraf_rev_panel.htm. However, all indications are that the outcome will not support the use of PBT criteria to evaluate the hazard and risk of metals. For example, in its October 23, 2002 Review of the EPA Metals Action Plan, a key step in the process under which the draft Metals Risk Assessment Framework is being developed, the SAB Panel stated its conclusion "that persistence is a problematic scientific issue for assessing metals

[1] Letter from Tom Fitzsimmons, Director, Department of Ecology, to Greg Hanon, March 5, 2002 (copy attached).

[2] *See* EPA, "Priority Chemicals and Fact Sheets," http://www.epa.gov/epaoswer/hazwaste/minimize/chemlist.htm.

[3] *Id*.

hazards and risks."[4] Similarly, the SAB concluded that "[w]hile bioaccumulation data can be useful for site-specific assessment of risk, bioaccumulation metrics such as BCF/BAF measures can be problematic for assessing generic metals hazard ranking." *Id*. Ecology's Draft PBT Rule relies on the use of both persistence and BCF/BAF metrics -- and the SAB has specifically called each of these approaches into question as a matter of science when used for metals. Expert issue papers that EPA commissioned in 2004 to examine the scientific considerations relating to hazard assessment of metals echoed the scientific concerns identified by the SAB's 2002 report regarding attempts to apply PBT criteria to metals.[5] Most recently, the SAB's draft report in its *Review of EPA's Draft Framework for Inorganic Metals Risk Assessment* (September 2005), available at http://www.epa.gov/sab/panels/mraf_rev_panel.htm, raised similar points, noting that "[t]he SAB agrees with the statement that BCF/BAFs do not apply for metals." Draft Report at 69 (paragraph 6.3.12.1).

Similar concerns have been expressed in other leading scientific reviews of this issue. For example, the recently published summary of the Society of Environmental Toxicology and Chemistry, *Assessing the Hazard of Metals and Inorganic Metal Substances in Aquatic and Terrestrial Systems* (2005),[6] pointed out scientific issues with the use of both persistence and bioaccumulation for evaluating hazard for metals. With regard to persistence, the SETAC report notes that "[t]raditional degradation mechanisms used for organic substances to evaluate persistence (or the converse, biodegradation) of metals have been criticized as inappropriate." *Id*. at 6. As for bioaccumulation, the report goes even further:

> Unlike organic substances, bioaccumulation potential of metals cannot be estimated using log octanol-water partition coefficients (Kow). Bioconcentration and bioaccumulation factors (BCFs and BAFs) are inversely related to exposure concentration and are not reliable predictors of chronic toxicity or food chain accumulation for most aquatic organisms and most metals. The inverse relationship between exposure concentration and BCF results in organisms from the cleanest environments (i.e., background) having the largest BCF or BAF values. This result is counterintuitive to the use of BCF and log Kow as originally derived for organic substances. [*Id*., citations omitted.]

For the foregoing reasons, NAMC urges Ecology not to include metals on the Proposed PBT List. Instead, NAMC recommends that Ecology insert the following language as a footnote to its PBT list:

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[4] *See* EPA-SAB-EC-LTR-03-001, *Review of Metals Action Plan: An EPA Science Advisory Report*, at 5, available at http://www.epa.gov/sab/fiscal03.htm.

[5] *See* http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=86119.

[6] WJ Adams, PM Chapman, eds., *Assessing the Hazard of Metals and Inorganic Metals Substances in Aquatic and Terrestrial Systems: Summary of a SETAC Pellston Workshop*, 2005.

Application of the Bioaccumulation criterion (a BCF >1,000) to metals has been called into question on the ground that BAF/BCF values are not meaningful for metals; instead, the BAF/BCF varies inversely with the concentration of the metal in water. Accordingly, Ecology will not make a decision whether to include mercury, cadmium and lead or other metals on the PBT list until after the U.S. Environmental Protection Agency ("U.S. EPA") concludes the process of preparing a Metals Risk Assessment Framework. This Framework will address the utility of using PBT criteria for evaluating the potential hazards of metals. The decision not to list metals does not mean, however, that Ecology or other state agencies will refrain from taking actions necessary to reduce risks to human health and the environment posed by the release or presence of mercury, cadmium and lead.

In addition to the foregoing comments, NAMC attaches an appendix containing more specific recommended changes to the Draft PBT Rule that we submit for Ecology's consideration.

Respectfully submitted,

William J. Adams, Ph.D., Chairman
North American Metals Council

Attachments

APPENDIX TO COMMENTS OF NORTH AMERICAN METALS COUNCIL

New Section Number	**Comment and Justification (in parentheses)**
WAC 173-333-100	In the second paragraph, second sentence, insert the words "where appropriate" in the phrase "there remains a need for multimedia, cross-program measures that will reduce and phase-out [,where appropriate,] releases and uses of PBTs over time." [Bracketed language reflects recommended addition.] (Explanation: As noted in the definition of the implementing "Chemical action plan," PBT substances will be subject to "actions to protect human health or the environment," language which recognizes the possibility that some may be capable of safe management with little or no risk to human health or in the environment; accordingly, the unqualified reference to a "phase-out" would not be scientifically justifiable or appropriate.) The same change is needed in the immediately following sentence, which falls in the third paragraph. In the third paragraph, third sentence, insert the words "having acceptable functionality," in the sentence: "These factors include environmental and human health benefits, economic and social costs, technical feasibility, availability of safer substitutes [having acceptable functionality], and consistency with other regulatory requirements." (Explanation: The term "substitutes" is not defined and it is important that it include some expectation that functionality is considered in determining whether a suggested alternative is actually a workable substitute.) This modification should also be made in WAC 173-333-42(f)(d).
WAC 173-333-200	The definitions of "Bioaccumulation factor" and "Bioconcentration factor" include identical first sentences, but these concepts are not the same. The words "including intake attributable to ingestion," should be added at the end of the first sentence of the definition of "Bioaccumulation factor." In the definition of "Credible scientific information," the word "accepted" should be used instead of "acceptable" in the phrase "information that is based on a theory or technique that is generally [accepted] in the relevant scientific community …." (Explanation: "Scientifically accepted" is the term customarily used in this context.) The definition of "feasible" should include the phrase "taking social and economic costs into account" at the end of the definition. (Explanation: This phrase provides some guidance that should be useful in interpreting the term.)

	In the definition of the term "Persistent bioaccumulative toxin" the word "criteria" is redundant the second time it is used and should be deleted.
WAC 173-333-310(2)	The PBT list is said to be composed of "chemicals" and "chemical groups," but the headings in the list specify "chemicals" and then "chemical categories." The word "categories" should be changed to "groups" in the list heading.
WAC 173-333-310(3), 173-333-320 (d)	Provisions relating to lead, mercury, cadmium, and metals should be modified as discussed in NAMC's main comments.
WAC 173-333-320 (2) (c)	The criterion for toxicity should be revised to add the following phrase to the end of subparagraphs (i) and (ii): "at concentrations or exposure levels that may reasonably be anticipated to occur in the State of Washington." (Explanation: The recommended language provides a nexus to a basis for concern by the state.)
WAC 173-333-420 (e)	In identifying policy options, the term "phasing-out" should be substituted for "eliminating." (Explanation: In most cases it will be necessary to allow a phase-out over a period of time, and this language is consistent with that used elsewhere in the proposed rule.)

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March 5, 2002

Mr. Greg Hanon
Communico Governmental Affairs
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Evergreen Plaza Building
711 Capitol Way South
Olympia, WA 98501

Dear Mr. Hanon:

The purpose of this letter is to respond to your request regarding the Environmental Protection Agency's (EPA) review of selected metals and Ecology's evaluation of that process for its "PBT Working List". Ecology's Persistent, Bioaccumulative Toxins (PBT) Working List serves as an agency reference for which PBTs we should focus on for future chemical action plans, and for the baseline monitoring program design. Ecology relied on a "PBT Characteristics" score developed by EPA to determine which chemicals to evaluate as the PBT Working List was developed.

Recently, it has come to our attention that EPA is in the process of updating their agency's waste minimization priorities as mandated by the Government Performance and Results Act. It is expected that an updated list of the highest priority PBTs slated for waste minimization priorities will be released later in Spring 2002. Included in these waste minimization priorities will be those metals that occur most frequently in RCRA waste streams or are part of international PBT reduction efforts. Ecology has learned that EPA will be working with its Science Advisory Board to develop comprehensive cross-agency guidance for assessing the hazards and risks of metals. Until this issue posed to EPA's Science Advisory Board is addressed, Ecology will include a footnote on any PBT Working List identifying that any metals on the working list are currently undergoing this review and that Ecology will revise any PBT working list so as to be consistent with EPA waste minimization treatment of metals.

The purpose of the PBT working list is to update and inform the public, regulated community, and other interested parties which PBTs are found in Washington. The PBT Working List will be updated periodically during the next several years as more data collected from Washington's environment becomes available and if EPA determines the need to refine, based on any new information, any "PBT characteristics" scores. In the past, Ecology has made it clear that we

intend to model closely EPA's process to ensure state consistency with nationally applied criteria and priorities.

If you have any further questions, please contact Mike Gallagher, Ecology's PBT Coordinator at 360/407-6868.

Sincerely,

Tom Fitzsimmons
Director

CC: Bill Backous, Program Manager - Environmental Assessment Program
Mike Gallagher, Ecology PBT Coordinator - Environmental Assessment Program
Greg Sorlie, Program Manager - Hazardous Waste and Toxics Reduction Program
Tom Eaton, Director - EPA Washington Operations Office